§ 80.34 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 80.39; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 80.39; or

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Any person who contests suspension of service shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

§ 80.35 Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in part 74 of this chapter, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restriction prescribed in parts 70 and 71 of this chapter.

(b) *Color additive mixtures exempted from certification.* A color additive mixture prepared from a previously certified batch of one or more straight colors, with or without any diluent that has been listed in part 73 of this chapter for use in mixtures, shall be exempt from batch certification if the straight color used has not changed in composition in any manner whatsoever since its certification and if it is simply mixed with the approved diluents for exempt mixtures. The label of such color additive mixtures shall not bear the lot number assigned by the Food and Drug Administration to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

(c) *Additions to the list of diluents.* A person requesting additions to the list of diluents authorized for the purposes described in paragraphs (a) and (b) of this section shall submit a petition in accordance with the provisions of § 71.1 of this chapter. Each such petition shall be accompanied by the fee prescribed in § 70.19 of this chapter, unless there is an advance deposit to be used for prepayment of such fees.

NOTE: The provisions of § 80.35 with respect only to diluents for use in cosmetic color additive mixtures were stayed, until a regulation is effected listing safe diluents for cosmetic use, including cosmetics which color the human body, 29 FR 18495, Dec. 29, 1964.

§ 80.37 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate has been issued.

§ 80.38 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been certified, the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(b) The person requesting certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 70.20 and 70.25 of this chapter, except

that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

§ 80.39 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Sec.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

§ 81.1 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 379e note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), and (c) of this section are provisionally listed until the closing dates set forth therein.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

Color additive	Closing date		Restrictions
	Food use	Drug and cosmetic use	
Lakes (FD&C) (sec. 82.51 of this chapter).			

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
Lakes (D&C) (Sec. 82.2051 of this chapter).		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Lakes (Ext. D&C) (sec. 82.105(1) of this chapter)		

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.1, see the List of CFR